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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,359	01/30/2004	Nicholas V. Perricone	00961-P0146D	6387
24126	7590	03/25/2005	EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619			KIM, VICKIE Y	
		ART UNIT		PAPER NUMBER
		1614		

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/768,359	PERRICONE, NICHOLAS V.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/2004</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____ .

## DETAILED ACTION

### ***Information Disclosure Statement(IDS)***

The information disclosure statement (IDS) is submitted on 1/30/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

### ***Claim Rejections - 35 USC § 102/103***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively obvious over Cole (US6444195) , Watson (US6482446) or Shapiro(US 6372791), alone.

The claims are drawn to a topical composition comprising an alkanolamine(e.g. dimethylaminoethanol, in an amount about 0.1-10%), tyrosine(0.01-6%) and a sulfur-containing ingredient (e.g. lipoic acid or glutathione or mixtures thereof, 0.01-10% ).

Firstly, Cole(US'195, hereinafter) teaches a topical composition used in the treatment of various skin disorders such as dermatoses and erythemas, skin cancer, or skin aging and so on. US'195 further teaches an active agents beneficially

incorporated into the patented composition to enhance the therapeutic effectiveness, wherein said active agents are comprising alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 4, lines 66-67 and col. 5, lines 14-34 and claims 17. Thus, all the critical elements required by the instant claims are well taught and the claims are anticipated by the cited reference.

Secondly, Shapiro et al(US'791) and Watson(US446) also teach very similar topical composition comprising all the ingredients required by the instant claims as well.

For example, US'791 teaches a topical composition comprising an alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 4, lines 20-43.

US'446 also teaches a topical composition comprising alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 3, lines 1-22.

Even if the claimed composition may not be included in the examples, and the weight amounts for these ingredients are not individually taught, it would have been readily apparent to any skilled artisan how to make the composition comprising such ingredients with titrating effective dosage for each active agent to maximize the therapeutic effectiveness within the given teaching(0.001-20%).

Thus, the claims are not patentably distinct over the prior art of the record.

It is noted that It is noted that the recitation(i.e. acne) has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

3. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively obvious over Perricone (US 6319942 or US6500857).

Because the claimed invention(US'942 or US'857) utilizes the composition comprising alknolamine derivatives(1-10%) such as esters of diethylaminoethanol, tyrosine(2-5%), lipoic acid(0.25-5%) , hydroxyl acid(e.g. glycolic acid, 3-7%), ascorbic acid derivatives(1-7%), and the instant claims also relates to a topical composition requires all the said ingredients(as active agents) taught by both patents , see abstract of US'942 and claims of US'857.

Thus, the scope of claimed invention of instant claims are encompassed by and thus, are not patentably distinct over the prior art of the record.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-11 of U.S. Patent No. 6319942 and 6500857. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention(US'857) utilizes the composition comprising alknolamine derivatives(1-10%) such as esters of diethylaminoethanol, tyrosine(2-5%), lipoic acid(0.25-5%) , hydroxyl acid(e.g. glycolic acid, 3-7%), ascorbic acid derivatives(1-7%), and the instant claims also relates to a topical composition requires all the said ingredients(as active agents) taught by the patent US'942 and US'857.

Thus, the scope of claimed invention in both patent and instant application are overlapping to each other and not patentably distinct.

### ***Conclusion***

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM  
PRIMARY EXAMINER

  
Vickie Kim  
March 21, 2005  
Art unit 1614